Obstetrics and Gynecology Devices Panel

STAN® S21 Fetal Heart Monitor, Neoventa, Inc. (P020001)

Monday, April 22, 2002

4/15/02 version of Draft Discussion Questions

Safety and Effectiveness

1. The pivotal clinical study supporting this PMA is a large multi-center randomized controlled trial (RCT) conducted in Sweden. The Swedish RCT was designed to compare several fetal and maternal outcome measures between women managed with STAN Monitor technology and women managed by conventional monitoring technology. Was the study design adequate?

2. The intent-to-treat analysis showed the following outcomes in the primary and secondary endpoints and other measures. Please discuss the clinical significance of these results.

Primary endpoint

	STAN (n=2159)	**control (n=2079)**	**p-value**
metabolic acidosis	0.7% (15)	1.5% (31)	0.02

Secondary endpoints and other measures

	STAN (n=2519)	**control (n=2447)**	**p-value**
all operative interventions for fetal distress	7.7% (193)	9.3% (227)	0.047
C-section, fetal distress	3.5% (87)	4.0% (97)	0.38
perinatal/intrapartum death*	0.08% (2)	0.04% (1)	

**excluding 1 perinatal death in each arm due to congenital anomalies*

3. Several issues identified in the FDA review may affect the results. Please discuss the implications of each issue.

   a) deviations from the RCT patient management protocol
   b) no registration of an ST Event
   c) exclusions based on inadequate recordings
   d) inter-country population and management differences
   e) re-training during the Swedish RCT

4. In addition to the Swedish RCT, the sponsor has conducted the following clinical studies using the STAN monitor. To what extent do results from these studies support the safety and efficacy of the STAN monitor?

   a) Plymouth RCT
   b) EU Study
   c) City of Gothenburg observational study

Labeling & Training

5. The sponsor proposed the following indication:

   Use of the STAN system is indicated when there is a planned vaginal delivery and:
   - there is need for close fetal surveillance during labor, or

- there are maternal disorders and/or utero-placental dysfunction with potential adverse influence on fetal oxygen and nutritional supply, or
- there is deviation from the normal course of labor including induction/augmentation of labor.

Does the PMA data support this indication for use? Do you have any suggestions for modifications?

6. Are the professional labeling and the training materials (section 1.a. of the Panel package) provided by the sponsor sufficient to ensure appropriate use of the STAN System?

Post market Studies

7. If the panel votes to recommend approval of the STAN monitor, is there a need for post approval studies? If so, what is the purpose of such studies and what are the key elements of the study design?

Definitions

Safety (21 CFR § 860.7(d)(1))

"There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks."

Effectiveness (21 CFR § 860.7(e)(1))

"There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results."

Valid Scientific Evidence (21 CFR § 860.7(c)(2))

"Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness."